



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-02-26

February 6, 2002

Ricardo Balda, CEO
Medicomp, Inc.
7845 Ellis Road
Melbourne, Florida 32904

Dear Mr. Balda:

During an inspection of your establishment located in Gainesville, Florida on December 10-12, 2001, FDA Investigator Ronald T. Weber determined that your establishment is a manufacturer and distributor of electrocardiographic monitors, model numbers, PM 350 and PM 20. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), electrocardiograph monitors are medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. During the inspection, the investigator documented violations of the Act causing the device to be adulterated within the meaning of section 501(h) of the Act. The Act requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the device is adulterated in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation as follows:

1. Your firm failed to validate significant manufacturing processes as required by 21 CFR 820.75(a). For example, there is no process validation for the new surface mount pick and place machine, and hand soldering operations used for all manufactured products (FDA 483, Observation #1).
2. Your firm failed to establish, document and maintain procedures for the monitoring and control of validated process parameters as required by 21 CFR 820.75(b). For example, there are no documented procedures for process validation (FDA 483, Observation #2).
3. Your firm failed to fully document corrective and preventive actions as required by 21 CFR 820.100(b). For example, there are no records documenting actions needed to correct and prevent occurrences of nonconforming product, verifying or validating corrective and preventive

actions, and disseminating information to individuals directly responsible for assuring the quality of products or the prevention of problems (FDA 483, Observation #s 3 & 4).

4. Your firm failed to verify or validate corrective and preventive actions to ensure that the actions are effective and do not adversely affect the finished device as required by 21 CFR 820.100(a)(4). For example, there is no record of the verification or validation of the correction to the J1 connector implemented in September 2001, and the hand solder reflow operation on the U-11 implemented in May 1999 (FDA 483, Observation #5
5. Your firm failed to implement and record changes in methods and procedures needed to correct and prevent identified quality problems as required by 21 CFR 820.100(a)(5). For example, there is no change control for the correction of the J1 connectors (FDA 483, Observation #6).
6. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30. For example, design input requirements were not documented (820.30(c); design review results, including identification of the design, were not documented and filed in a design history file (820.30(e); procedures were not defined for the identification of design changes before their implementation (820.30(i); procedures for validating the device design were not defined and complete (820.30(g); and procedures were not established to ensure that the device design was correctly transferred into production (820.30(h) (FDA 483, Observation #s7-11).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

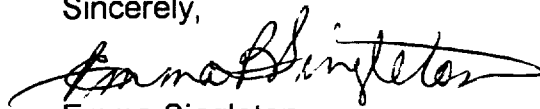
Copies of your firm's written responses dated January 8 and February 2, 2002 were received and reviewed. Your response states that some of the corrections are in-process and will not be complete until March 29, 2002. We also understand that your firm will be validating the pick and place machine, which is not addressed in your

responses except to say it is complete. Your February 2nd response addresses the U-11 reflow process, however, you state that retrospective validation will be used to correct the problem. Generally, retrospective validation is helpful in identifying a problem, however, your response fails to address the validation you will conduct to ensure that any changes are effective and do not affect the finished device. Your responses should not only address the specific observation made, but also the system impacted by the deficiency and provide documentation for our review. Lastly, you did not provide examples of the training files that were returned to your facility for our review. Your responses have been made part of the Florida District files.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of further steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton", with a stylized flourish extending from the end.

Emma Singleton

Director, Florida District